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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,515	06/12/2001	Billy W. Colston	IL-10715	5330

7590 10/29/2003

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EXAMINER	
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ART UNIT	PAPER NUMBER
1639	16

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/880,515	Applicant(s) COLSTON ET AL.	
	Examiner My-Chau T. Tran	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 36-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment filed 8/07/03 in Paper No. 15 is acknowledged and entered. Claims 1-9, and 36-43 are amended by the amendment.

2. Claims 1-9, and 36-43 are pending.

Withdrawn Rejections

3. The previous objection for claim 41 has been withdrawn in view of applicant's amendments of claim 41.

4. The previous rejections under 35 USC 112, first paragraph (new matter), for claims 1-9 and 36-40 have been withdrawn in view of applicant's amendments of claims 1-9 and 36-40.

5. The previous rejections under 35 USC 112, second paragraph, for claims 1-9 and 36-43 have been withdrawn in view of applicant's amendments of claims 1-9, and 36-43.

6. Claims 1-9, and 36-43 are treated on the merit in this Office Action.

Maintained Rejections

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

8. Claims 1-3, 5-6, 36 and 40 are rejected under 35 U.S.C. 102(b) as being anticipate by Pyle et al. (US Patent 5,821,066).

The instant claimed method of claim 1 recites a method for pathogen detection composed of sequential operations. The sequential method steps comprise: 1) containing optically encoded microbeads; 2) adding a sample and capture ligand to the contained microbeads; 3) placing the contained microbeads in a mixing holder for sufficient time for the targeted biological sample to adequately bind the microbeads; 4) adding fluorescent labeled antibodies for attachment to the microbead bound sample; 5) attaching the microbeads to a disposable capture substrate containing an array of attachment sites for attaching the microbeads thereto; 6) washing the substrate and attached microbeads; 7) inserting the substrate into an optical detection system for optically decoding the microbeads for identification and measurement of the target biological molecules. It is interpreted that steps 2-4 is the method of making the product use in step 1.

Pyle et al. disclose a method for the detection, identification and enumeration of a respiring target bacterium comprising the steps of: a) mixing immunomagnetic beads comprising an antibody (capture ligand) which specifically binds to a target bacteria with a liquid sample comprising said target bacteria; b) allowing said liquid sample to interact with the beads for up to an hour (step a) and b) would refer to step 2) and 3) of the instant claimed method, which would result in step 1) of the instant claimed method); c) placing the sample in a magnetic separator which causes the magnetic beads to which target bacteria have attached to separate from the liquid sample (referring to step 5); d) aspirating the liquid from the liquid sample, leaving the beads with bacteria attached; e) washing the beads with a solution which removes loosely bound

bacteria and other particles from the liquid sample (referring to step 6 and claim 6); f) mixing beads with bacteria attached with a fluorochrome dye specific for the detection of respiring bacteria; g) treating bacteria on the beads with a fluorescent stain or a specific fluorescent conjugated antibody (either step f) or g) would refer to step 4)); h) mounting said sample for examination by epifluorescent microscopy, in which a suitable light filter system is used to excite the fluorochrome dye and fluorochrome labeled antibody to fluoresce; and i) quantifying said respiring target bacteria (step h) and i) would refers to step 7 of the presently claimed invention) (col. 12, lines 42-67 to col. 13, line 1). Further, following or simultaneously with incubation with the respiratory indicator, cells on the beads may be treated with a fluorescent stain or a specific fluorescent conjugated antibody (col. 18, lines 2-5). Therefore, either step f) and/or g) would precede step c). The sample is mounted by way of trapping the beads on a filter membrane and optically read (col. 14, lines 4-20). This would then provide the array pattern on such a membrane (referring to claim 5). The sample suspension containing the beads is allowed to interact for up to an hour, with gentle agitation (col. 17, lines 56-58) (referring to claim 3). Then the method of Pyle et al. anticipates the instant claimed sequential method.

The amendments of claim 1 wherein the deletion of "*the sequential operations*" would not overcome the method of Pyle et al. but rather the rejections under 35 USC 112, first paragraph (new matter). The additional steps of providing microbeads wherein the microbeads contained capture ligand and/or bioagent-specific antibodies are inherit steps of the method of Pyle et al. Therefore, the method of Pyle et al. anticipates the instant claimed method.

Response to Arguments

9. Applicant's argument directed to the above rejection under 35 USC 102(b) as being anticipated by Pyle et al. (US Patent 5,821,066) for claims 1-3, 5-6, 36 and 40 was considered but they are not persuasive for the following reasons.

Applicant contends that the method of Pyle et al. does not anticipates the presently claimed method because "[T]he Pyle et al. reference describes a rapid method for detection, identification and enumeration of specific respiring microorganisms" wherein the method includes the steps disclose in the abstract. Therefore the method of Pyle et al. does not anticipate the presently claimed method.

Applicant's arguments are not convincing since the method of Pyle et al. does anticipate the presently claimed method. The reference of Pyle et al. discloses several different methods of detecting microorganism and one such method disclosed anticipate the presently claimed method (col. 12, lines 42-67 to col. 13, line 1). Additionally, it is noted that "*The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain.*" *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968))" (see MPEP 2123). Therefore the method of Pyle et al. does anticipate the presently claimed method.

Claim Rejections - 35 USC § 103

10. Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pyle et al. (US Patent 5,821,066) and Nazareth et al. (US Patent 6,319,676 B1).

The instant claimed method of claim 1 recites a method for pathogen detection composed of sequential operations. The sequential method steps comprise: 1) containing a quantity of microbeads; 2) adding a sample and capture ligand to the contained microbeads; 3) adding fluorescent labeled antibodies for attachment to the microbead bound sample; 4) providing a disposable capture substrate containing an array of attachment sites for attaching the microbeads thereto; 5) inserting the disposable capture substrate containing the array of attachment sites into the contained microbeads for capturing the microbeads; and 6) inserting the substrate into an optical detection system for optically decoding the microbeads for identification and measurement of the target biological molecules. Additionally including the contained quantity of microbeads to be optically encoded (Claim 42). It is interpreted that steps 1-3 is the method of making the product use in the claimed method step 42. Thus, claim 43 is a duplicate of step 6 in claim 41.

Pyle et al. disclose a method for the detection, identification and enumeration of a respiring target bacterium comprising the steps of: a) mixing immunomagnetic beads comprising an antibody (capture ligand) which specifically binds to a target bacteria with a liquid sample comprising said target bacteria; b) allowing said liquid sample to interact with the beads for up to an hour (step a) and b) would refer to step 1) and 2) of the instant claimed method, which would result in step 1) of the instant claimed method); c) placing the sample in a magnetic separator which causes the magnetic beads to which target bacteria have attached to separate from the liquid sample (referring to step 4); d) aspirating the liquid from the liquid sample, leaving the beads with bacteria attached; e) washing the beads with a solution which removes loosely bound bacteria and other particles from the liquid sample; f) mixing beads with bacteria attached with a

fluorochrome dye specific for the detection of respiring bacteria; g) treating bacteria on the beads with a fluorescent stain or a specific fluorescent conjugated antibody (either step f) or g) would refer to step 3)); h) mounting said sample for examination by epifluorescent microscopy, in which a suitable light filter system is used to excite the fluorochrome dye and fluorochrome labeled antibody to fluoresce; and i) quantifying said respiring target bacteria (step h) and i) would refers to step 6 of the presently claimed invention) (col. 12, lines 42-67 to col. 13, line 1). Further, following or simultaneously with incubation with the respiratory indicator, cells on the beads may be treated with a fluorescent stain or a specific fluorescent conjugated antibody (col. 18, lines 2-5). Therefore, either step f) and/or g) would precede step c).

The amendments of claim 41 wherein the deletion of "*the sequential operations*" would not overcome the method of Pyle et al. but rather the rejections under 35 USC 112, first paragraph (new matter). The additional steps of providing microbeads wherein the microbeads contained capture ligand and/or bioagent-specific antibodies are inherit steps of the method of Pyle et al.

The method of Pyle et al. does not expressly disclose the method step of inserting the disposable capture substrate into the contained microbeads for capturing the microbeads.

Nazareth et al. disclosed a device and method for detecting the presence of analyte in the body fluids (col. 1, lines 44-46). The assay method comprise of a dipstick for dipping in a container of test solution (col. 8, lines 28-30) and a capture site wherein a complex is form comprising immobilized capture agent-capturable conjugate-analyte-labeled binding member (col. 8, lines 45-47).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the method step of inserting the disposable capture substrate into the contained microbeads for capturing the microbeads as taught by Nazareth et al. in the method of Pyle et al. One of ordinary skill in the art would have been motivated to include the method step of inserting the disposable capture substrate into the contained microbeads for capturing the microbeads in the method of Pyle et al. for the advantage of providing an assay system which involves a minimal number of procedural steps, and reproducibility yields reliable results even when used by untrained persons (Nazareth: col. 1, lines 48-50).

Response to Arguments

11. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Pyle et al. (US Patent 5,821,066) and Nazareth et al. (US Patent 6,319,676 B1) for claims 41-43 was considered but they are not persuasive for the following reasons.

Applicant alleges that the combination of the method of Pyle et al. and the method of Nazareth et al. is non-obvious over the presently claimed method because the method of Pyle et al. does not disclosed the method steps of the presently claimed method and the method of Nazareth et al. does not cure the deficiencies.

Applicant's arguments are not convincing since the combination of the method of Pyle et al. and the method of Nazareth et al. is obvious over the presently claimed method. The reference of Pyle et al. discloses several different methods of detecting microorganism and one such method disclosed anticipate the presently claimed method (col. 12, lines 42-67 to col. 13, line 1). Additionally, it is noted that "*The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned.*

They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968))" (see MPEP 2123). Therefore the combination of the method of Pyle et al. and the method of Nazareth et al. is obvious over the presently claimed method.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-9, and 36-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The presently claimed method recites a method for pathogen detection for a targeted biological sample. The instant claim 1 briefly recites the method steps of providing optically encoded microbeads wherein the microbeads contained either capture ligand and/or bioagent-specific antibodies; containing the optically encoded microbeads; adding a sample to the contained microbeads; placing the contained microbeads and sample in a mixing holder for sufficient time for the targeted biological sample to adequately bind the microbeads; adding fluorescent labeled antibodies to the contained microbeads and sample for attachment to the

bioagent-specific antibodies; attaching the microbeads to a disposable capture substrate; washing the substrate and attached microbeads; inserting the substrate into an optical detection system; and optically decoding the microbeads for identification and measurement of the targeted biological sample.

The method step recitation of *'adding fluorescent labeled antibodies to the contained microbeads and sample for attachment to the bioagent-specific antibodies'* (e.g. the fluorescent labeled antibodies is attached to the bioagent-specific antibodies) claimed in claim 1, has no clear support in the specification and the claims as originally filed. The specification in page 11, paragraph [0038], and figures 4-6 disclosed the method step of '*The fluorescent reporter labeled antibodies are added to cuvet that attach to the microbead bound sample*' (lines 8-10) (e.g. the fluorescent labeled antibodies is attached to the "sample" (targeted biological sample)) is not support for '*adding fluorescent labeled antibodies to the contained microbeads and sample for attachment to the bioagent-specific antibodies*'. Figures 4-5 disclose that the sample (targeted biological sample) is attached to the microbeads via the bioagent-specific antibodies (see figure 4), and the fluorescent labeled antibodies is attached to the sample. Because the narrow limitation of the specification recites that the fluorescent reporter labeled antibodies are attached to the sample, it does not support the limitation of the claim, which recites that the fluorescent labeled antibodies are attached to the bioagent-specific antibodies. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation that the fluorescent labeled antibodies are attached to the bioagent-specific antibodies.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

14. Claims 41-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The presently claimed method recites a method for pathogen detection for biological molecule. The instant claim 41 briefly recites the method steps of providing optically encoded microbeads; adding the capture ligand to the microbeads; adding the bioagent-specific antibodies to the microbeads; containing the microbeads; adding a sample to the contained microbeads; adding fluorescent labeled antibodies for attachment to the bioagent specific antibodies; providing a disposable capture substrate; inserting the disposable capture substrate into the contained microbeads for capturing the microbeads; washing the substrate and attached microbeads; inserting the substrate into an optical detection system; optically decoding the microbeads for identification and measurement of the biological molecules attached to the microbeads.

The method step recitation of '*adding fluorescent labeled antibodies for attachment to the bioagent specific antibodies*' (e.g. the fluorescent labeled antibodies is attached to the bioagent-specific antibodies) claimed in claim 1, has no clear support in the specification and the claims as originally filed. The specification in page 11, paragraph [0038], and figures 4-6 disclosed the method step of '*The fluorescent reporter labeled antibodies are added to cuvet that attach to the microbead bound sample*' (lines 8-10) (e.g. the fluorescent labeled antibodies is attached to the "sample" (targeted biological sample)) is not support for '*adding fluorescent*

labeled antibodies for attachment to the bioagent-specific antibodies'. Figures 4-5 disclose that the sample (targeted biological sample) is attached to the microbeads via the bioagent-specific antibodies (see figure 5), and the fluorescent labeled antibodies is attached to the sample (see figure 6). Because the limitation of the specification recites that the fluorescent reporter labeled antibodies are attached to the sample, it does not support the limitation of the claim, which recites that the fluorescent labeled antibodies are attached to the bioagent-specific antibodies. Therefore, the invention as originally disclosed in the specification would not encompass the claimed limitation that the fluorescent labeled antibodies are attached to the bioagent-specific antibodies.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

15. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter is which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The instant claim 7 briefly recites the method step "*wherein said step of containing said microbeads is carried out by placing said microbeads in a disposable bead pack*".

The recitation of '*wherein said step of containing said microbeads is carried out by placing said microbeads in a disposable bead pack*' claimed in claim 7, have no clear support in the specification and the claims as originally filed. The specification in page 11, paragraph [0038] disclosed '*sample is added to a cuvet containing optically encoded microbeads*' (lines 2-

3) is not support for '*wherein said step of containing said microbeads is carried out by placing said microbeads in a disposable bead pack*'. Because the specification recites that the method is performed by containing the microbeads in a cuvet, it does not support the claimed limitation of the claim 7, which recites that the method is performed by containing the microbeads in a disposable bead pack. Therefore, the invention as originally disclosed in the specification would not encompass the claimed limitation of claim 7 of method step "*wherein said step of containing said microbeads is carried out by placing said microbeads in a disposable bead pack*".

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 1-9, and 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 is vague and indefinite with regard to the correlation between "pathogen detection" and "targeted biological sample". The term "targeted biological sample" would encompass the term "pathogen".

b. Claim 1 is vague and indefinite with regard to the correlation between the method step of "optically decoding said microbeads for identification and measurement of said

targeted biological sample" and the "method for pathogen detection for a targeted biological sample".

c. Claim 1 is vague and indefinite with regard to the relationship of the "capture ligand" with regard to the "targeted biological sample", and the "substrate".

d. The method steps of providing a multiplicity of optically encoded microbeads; providing said microbeads with a capture ligand; and providing said microbeads with bioagent-specific antibodies of claim 1 are vague and indefinite. It is unclear whether the microbeads are optically encoded and have either capture ligand and/or bioagent-specific antibodies or that there is a mixture of microbeads wherein the mixture of microbeads comprise of microbeads that are optically encoded, microbeads that has capture ligand, and microbeads that has bioagent-specific antibodies.

e. It is unclear as to the relationship between "capture ligand" and "bioagent-specific antibodies" of claim 1. The term "capture ligand" is synonymous with the term "bioagent-specific antibodies".

f. Claim 8 is vague and indefinite because it does not further limit claim 1. The claimed method steps of claim 8 are redundant with the claimed method steps of claim 1. For example, claim 8 claimed a limitation of additionally including the step of an assay, but the method of claim 1 is an assay.

g. Claim 9 is vague and indefinite because it does not further limit claim 1. The claimed step of processing of claim 9 is the summation of the claimed method steps of claim 1.

h. Claim 41 is vague and indefinite with regard to the correlation between "pathogen detection" and "biological molecules". The term "biological molecules" would encompass the term "pathogen".

i. Claim 41 is vague and indefinite with regard to the correlation between the method step of "optically decoding said microbeads for identification and measurement of said biological molecules attached to said microbeads" and the "method for pathogen detection for a targeted biological sample".

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999.

The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
October 27, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER